PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference PZ0219/PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB 02/05604	International filing date *(day/month/year)* 11.12.2002	Priority date *(day/month/year)* 11.04.2002
International Patent Classification (IPC) or both national classification and IPC G21G1/00		
Applicant AMERSHAM PLC et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17.10.2003	21.09.2004
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Deroubaix, P Telephone No. +49 89 2399-7592

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB 02/05604

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-16 as originally filed

Claims, Numbers

1-17 as originally filed

Drawings, Sheets

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-3,6-7,9-10,12
Inventive step (IS)	Yes:	Claims	
	No:	Claims	4-5,8,11,13-17
Industrial applicability (IA)	Yes:	Claims	1-17
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1:FR-A-2 194 021 (HOECHST AG) 22 February 1974 (1974-02-22)
D2:US-A-3 564 256 (NONHEBEL DIRK ET AL) 16 February 1971 (1971-02-16) cited in the application

1. OBJECTIONS AS TO CLARITY (ARTICLE 6 PCT)

It is clear from the description on page 9 that the following feature is essential to the definition of the invention: "The tube 6 containing the ion exchange column has frangible rubber seals 8 and 9 at opposing ends 10 and 11 which when in use are pierced by respective hollow needles 12 and 13".

Since independent claims 1 and 14 do not contain this feature, they do not meet the requirement following from Article 6 PCT taken in combination with Rule 6.3(b) PCT that any independent claim must contain all the technical features essential to the definition of the invention.

The terms "buffer" and "spacer" used in the claims are not clear. In the description, the phrase: "The spacer is provided with the second compressible buffer..." (page 6, lines 11-12) leads to doubt as to the fact whether the buffer is part of the spacer or not. In independent claim 14 the phrase "one or each of the compressible buffers including a spacer of predetermined thickness" is more precise in this respect, but is not clear either. In claim 1 the phrase: "a spacer of a predetermined thickness associated with one or each of the first and second compressible buffers..." is not clear either.

In order to dispel any ambiguity it would be appropriate to remove the terms "buffer" and "spacer" from the claims, to introduce the more precisely defined "disks" appearing in the description and to state clearly their arrangement in the device.

In claim 1, the phrase: "for determining the positioning of the isotope container within the shielded chamber" relates to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.

In claims 4 and 5 the terms "semi-open cell foam" and "closed cell foam" respectively are not clear. A definition of the terms is missing.

In claim 14, the order of completion of the individual steps of the method appears to be of importance. This should become more apparent from the wording of said claim. In this connection it should be pointed out that the second step of the method appears to be impractical. As a matter of fact, the hollow needle projecting from the chamber closure cannot project into the shielded chamber as long as said shielded chamber has not been closed (Article 6 PCT).

Furthermore, independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (documents cited in the search report or any documents known to the applicant) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

Independent claim 1 should therefore be redrafted accordingly. If, however, the applicant is of the opinion that the two-part form would be inappropriate, then reasons therefor should be provided in the letter of reply. In addition, the applicant should ensure that it is clear from the description which features of the subject-matter of claims 1 and 14 are already known in combination from the prior art documents (see the PCT Guidelines, III-2.3a).

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

2. OBJECTIONS AS TO NOVELTY (ARTICLE 33(2) PCT)

Claim 1

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and insofar as this claim can be understood, this document shows the following features thereof (the references in parentheses applying to this document):
a device for producing a fluid containing a radioactive constituent, the device comprising (see figures 2 and 7 of D1)

a shielded chamber (14) with an opening for receiving an isotope container (13) housing a radioactive isotope;

a chamber closure adapted for cooperating with and closing the chamber opening;
a first fluid port comprising a first hollow needle (15) projecting into the shielded chamber from the chamber closure for fluid communication with the isotope container;
a second fluid port comprising a second hollow needle (15) projecting into the shielded chamber from the closed end of the chamber opposite the chamber closure for communication with the isotope container;
first and second compressible buffers (to be seen on figure 1, one of them being shown in more detail on figure 7) mounted so as to surround at least partially the respective first and second hollow needles, each buffer providing an outer surface for contact with opposed ends of the isotope container; and
a spacer of a predetermined thickness associated with one or each of the first and second compressible buffers for determining the positioning of the isotope container within the shielded chamber.

The subject-matter of claim 1 is therefore not new.

Claim 2

In the device of D1, when the chamber closure is in place in the chamber opening, the first and second hollow needles are fixed in position at each end of the shielded chamber.

The subject-matter of claim 2 is therefore not new.

Claim 3

In the device of D1, the spacer is provided with the second compressible buffer at the closed end of the shielded chamber.

The subject-matter of claim 3 is therefore not new.

Claim 6

The device of D1 is a radioisotope generator.

The subject-matter of claim 6 is therefore not new.

Claim 7

In the device of D1, opposing ends of the isotope container each includes a frangible seal adapted to be pierced by and to seal around the respective first and second hollow needles.

The subject-matter of claim 7 is therefore not new.

Claim 9

In the device of D1, the first and second hollow needles are each connected via associated fluid conduits with a fluid inlet and a fluid outlet respectively.

The subject-matter of claim 9 is therefore not new.

Claim 10

In the device of D1, the fluid inlet and the fluid outlet each consists of hollow spikes (3,18).

The subject-matter of claim 10 is therefore not new.

Claim 12

In the device of D1, the fluid conduits each consists of a flexible tubing (12,17a) which is greater in length than the distance between the hollow needles and their respective inlet and outlet.

The subject-matter of claim 12 is therefore not new.

3. OBJECTIONS AS TO INVENTIVE STEP (ARTICLE 33(3) PCT)

The above-mentioned lack of clarity notwithstanding, the inventive step involved in claims 4,5,8,11,13-17 appears to be questionable.